



ADVANCED BIO-SURFACES, INC.

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## 510(k) Summary

**Advanced Bio-Surfaces, Inc.**

**Orthoglide® Medial Knee Implant**

**510(k) Notification** K053094

### MANUFACTURER INFORMATION

**Name & Address:** Advanced Bio-Surfaces, Inc.  
5909 Baker Road  
Minnetonka, MN 55345 USA

**Summary Prepared:** November 2, 2005

**Contact:** Philip B. Jarvi  
Director, Q.A. / Regulatory Affairs  
952-912-5400 phone  
952-912-5410 fax

### DEVICE INFORMATION

**Trade Name:** Orthoglide® Medial Knee Implant

**Classification Name:** 21CFR 888.3590 – Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis

**Product Code:** HSH

**Common / Usual Name:** Hemi- knee prosthesis

**Substantial equivalence:** The ABS Orthoglide® Medial Knee Implant is substantially equivalent to FDA approved predicate devices with regard to indications for use, materials, technological characteristics and surgical techniques. These predicate devices are: Sulzer Orthopedics, Inc. Unicondylar Interpositional Spacer (K003269)  
ITI, Knee Interpositional Mini-Repair system (KIMRS) (K033242)

**Device Description:** The Orthoglide Medial Knee Implant is placed in the medial compartment of the knee between the tibial plateau and femoral condyle by means of minimally invasive surgery. The instruments are intended to aid in the surgical preparation of the implant site and implant placement. The Orthoglide is made of a Cobalt-Chrome-Molybdenum Alloy. Device geometry and ligament tension combine to keep the implant in place. The implant covers the tibial plateau. The device is designed to improve the alignment of the knee, returning the joint to a more valgus position. Realignment of the knee distributes the weight-bearing forces across the joint and helps restore the normal relationships of the articular surfaces and the surrounding capsular, ligamentous and muscular structures.

The device is designed to help relieve pain by providing an articulating surface with a low coefficient of friction and high durability. Device geometry improves knee alignment and joint spacing. The device surface is smooth and when wet, is intended to mimic the lubricious surface previously provided by the articular cartilage.

**Intended Use:** The Orthoglide Medial Knee Implant is intended for use in the osteoarthritic knee, where a substantial amount of cartilage has been lost as a result of the disease. The device is indicated for uncemented use in the treatment of moderate degeneration of the medial compartment of the knee (grade II-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral and patellofemoral compartments in patients with osteoarthritis.

**Substantial Equivalence:** The ABS Orthoglide Medial Knee Implant is substantially equivalent to FDA approved predicate devices with regard to indications for use, materials, technological characteristics and surgical techniques. Orthoglide offers no additional risks to the patient and the materials and manufacturing methods add no new or additional safety concerns. The Orthoglide as well as the predicates are submitted without clinical information. The substantially equivalent predicate devices are:

Sulzer Orthopedics, Inc. Unicondylar Interpositional Spacer (K003269)

ITI, Knee Interpositional Mini-Repair system (KIMRS) (K033242)

**Testing:** The Orthoglide Implant has been developed, verified and validated in compliance with a comprehensive design process. The corresponding Bench Testing has been accomplished according to a Master Test Plan for the device. The test plan shows the required test, the source of the requirement, the protocol and the report. If the method is from a standard, the voluntary standard is referenced. The bench testing has demonstrated the physical attributes and durability of the Orthoglide by tensile elongation, load deflection, cyclic fatigue resistance, material consistency and stability and processing control. Cadaver testing has verified the surgical technique and instruments. Cadaver evaluations have also verified the desired physiological effects of stability, angular correction and range of motion preservation.

The Orthoglide also demonstrated that it meets internationally recognized standards for biocompatibility (ISO 10993), sterility (EN550), and conformance to material specifications. Clinical testing was not used to determine substantial equivalence.

**Summary:** Based on the evidence of substantial equivalence the Orthoglide is considered to safe and effective and will perform as well or better than the referenced predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 6 2006

Mr. Philip B. Jarvi  
Director, Q.A./Regulatory Affairs  
Advanced Bio-Surfaces, Inc.  
5909 Baker Road  
Minnetonka, Minnesota 55345

Re: K053094  
Trade/Device Name: Orthoglide Medial Knee Implant  
Regulation Number: 21 CFR 888.3590  
Regulation Name: Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis  
Regulatory Class: II  
Product Code: HSH  
Dated: January 19, 2006  
Received: January 20, 2006

Dear Mr. Jarvi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Acting Director  
Division of General, Restorative and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K053094

Device Name: Orthoglide® Medial Knee Implant

Indications for Use:

The Orthoglide Medial Knee Implant is intended for use in the osteoarthritic knee, where substantial amounts of cartilage have been lost as a result of the disease.

The device is indicated for uncemented use in the treatment of moderate degeneration of the medial compartment of the knee (grade II-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral and patellofemoral compartments in patients with osteoarthritis.

Prescription Use Yes  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division General Restorative  
and Neurological Devices

(Posted November 13, 2003)

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